Notice of Allowability	Application No.	Applicant(s)	
	10/036,988	PAPKE, ROGER L.	
	Examiner	Art Unit	
	Brian S Kwon	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *Amendment filed 6/25/2004 and Telephonic Interview on 8/25/2004*.

2. ☒ The allowed claim(s) is/are *1,4,5 and 7-10*.

3. ☒ The drawings filed on *12/31/01 and 6/25/2004* are accepted by the Examiner.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *8/25/2004* .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

DETAILED ACTION

1. Acknowledgement is made of applicant's filing of replacement drawing sheet containing Figure 6A and 6B.

EXAMINER'S AMENDMENT

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Glen P. Ladwig on August 25, 2004.

The application has been amended as follows:

Rewrite the claims 1, 4-5, 7 and 9-10 as following:

Claim 1 (Currently amended): A method for reducing an adverse effects associated with administration of 3-[2,4-dimethoxybenzylidene]-anabaseine (GTS-21), wherein said method comprising co-administering metanicotine or a pharmaceutically acceptable salt thereof, with 3-[2,4-dimethoxybenzylidene]-anabaseine (GTS-21) or a pharmaceutically acceptable salt thereof, to a patient in need thereof.

Claim 2 (Cancelled)

Claim 3 (Currently cancelled)

Claim 4 (Currently amended): The method, according to claim 1, wherein the metanicotine, or pharmaceutically acceptable salt thereof, and the 3-[2,4-dimethoxybenzylidene]-anabaseine (GTS-21) are administered to the patient simultaneously.

Claim 5 (Currently amended): The method, according to claim 1, wherein the metanicotine, or pharmaceutically acceptable salt thereof, and the 3-[2,4-dimethoxybenzylidene]-

anabaseine (GTS-21) are administered to the patient simultaneously and in the form of a pharmaceutical composition.

Claim 6 (Cancelled)

Claim 7 (Currently amended): The method, according to claim 1, wherein the patient is suffering from the neurological condition selected from the group consisting of Alzheimer's disease, Parkinson's disease, Huntington's chorea, tardive dyskinesia, hyperkinesias, mania, attention deficit disorder, attention deficit hyperactivity disorder, sleep-wake disorder, chronic-fatigue syndrome, tremor, epilepsy, neuropathic pain, addiction, anxiety, dyslexia, schizophrenia, obsessive-compulsive disorder, Tourette's syndrome and a combination thereof.

Claim 8 (Original): The method, according to claim 1, wherein the route of administration is selected from the group consisting of intravenous, oral, and intra-nasal.

Claim 9 (Currently amended): The method, according to claim 1, wherein the metanicotine, or pharmaceutically acceptable salt thereof, and the 3-[2,4-dimethoxybenzylidene]-anabaseine (GTS-21) administered to the patient do not cause an adverse side effect in the patient which is normally associated with administration of the -3-[2,4-dimethoxybenzylidene]-anabaseine (GTS-21) alone, or wherein the metanicotine, or pharmaceutically acceptable salt thereof, and the 3-[2,4-dimethoxybenzylidene]-anabaseine (GTS-21) administered to the patient cause an adverse side effect in the patient which is normally associated with administration of the 3-[2,4-dimethoxybenzylidene]-anabaseine (GTS-21) alone, but of decreased intensity.

Claim 10 (Currently amended): The method, according to claim 1, wherein the metanicotine, or pharmaceutically acceptable salt thereof, and the 3-[2,4-dimethoxybenzylidene]-anabaseine (GTS-21) are administered in amounts sufficient to penetrate the blood-brain barrier.

Claims 11-20 (Cancelled)

CONCLUSION

3. Claims 1, 4-5 and 7-10 are allowed.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951. The fax number for this Group is (703) 872-9306.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

VICKIE KIM
PRIMARY EXAMINER

Brian Kwon
Patent Examiner
AU 1614